CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-334 *and* 21-085/S-010

CORRESPONDENCE

Bayer

Pharmaceutical Division

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone: 203 812-2000

April 20, 2001

Mark Goldberger, M.D., M.P.H., Director
Division of Special Pathogens and Immunologic Drug Products
Office of Drug Evaluation IV (HFD-590)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

Re: NDA 21-334
AVELOX® (moxifloxacin hydrochloride) Tablets
Response to FDA Request – Debarment Certification

Dear Dr. Goldberger,

Bayer Corporation, Pharmaceutical Division acknowledges a request made by Valerie Jensen, Project Manager for a revised debarment certification for NDA 21-334.

In this response, Bayer provides a revised debarment certification for the NDA file. It incorporates all specific requests concerning the studies submitted to support this new drug application.

If any questions or concerns arise from this information, do not hesitate to contact me at (203) 812-5172 or Ms. Robin M. Christoforides at (203) 812-2112.

Sincerely,

Andrew S. Verderame
Deputy Director, Regulatory Affairs

Desk Copy: Valerie Jensen, R.Ph., Project Manager

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-334

Bayer Corporation
Attention: Andrew Verderame
Associate Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Mr. Verderame:

We acknowledge receipt on October 27, 2000 of your October 26, 2000 resubmission to your new drug application (NDA) 21-085 for Avelox™ (moxifloxacin hydrochloride) 400 mg tablets. Please note, as Valerie Jensen explained by telephone, that the number NDA 21-334 has been assigned to this resubmission for our administrative purposes. Once a final action is taken on this resubmission, this number will be retired and all future correspondence should refer to 21-085.

This resubmission contains additional data from Phase 4 studies regarding the safety of moxifloxacin hydrochloride tablets. This data was submitted to demonstrate an acceptable risk benefit profile regarding the indication of uncomplicated skin and skin structure infections in response to our December 10, 1999 action letter.

We consider this a complete class 2 response to our action letter. Therefore, the user fee goal date is April 27, 2001.

If you have any questions, call Valerie Jensen, R.Ph., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research